HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

M2604.1

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

May 4, 1999

WARNING LETTER
CIN-WL-99-207

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr.Steve Fricke
Vice President/General Manager
Buckley Brothers, Inc.
320 E. Main Street
P.O. Box 845
Wilmington, OH 45177

Dear Mr. Fricke:

An inspection of your animal feed manufacturing operation located at Wilmington, Ohio conducted by a Food and Drug Administration Investigator on March 29 and April 12, 1999, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. The regulation is intended to prevent the establishment and amplification of transmissible spongiform encephalopathies (TSE's). Such deviations cause products being manufactured at this facility to be misbranded within the meaning of Section 403(f) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found a failure to label your product with the required statement "Do Not Feed to Cattle or other Ruminants". The FDA suggests the statement be distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by a purchaser.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Although a copy was provided during the June 1998 inspection, we have enclosed a copy of the FDA's Small Entity Compliance Guide No. 68 to assist you with complying with the regulations.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without future notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention Leonard Jay Farr, Compliance Officer.

Sincerely yours,

Henry L. Fielden
District Director

Enclosure: Small Entity Compliance Guide #68

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